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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,086	11/25/2003	Brian J. Lancaster	CRNI.111056	4915

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EXAMINER	
LUBIN, VALERIE	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
03/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,086	LANCASTER ET AL.	
	Examiner	Art Unit	
	VALERIE LUBIN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 28-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26, 28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 1-26 and 28-34 are pending

For reference purposes, the document paper number is 20090217

Response to Amendment

2. Applicant's arguments with respect to claims 1-26 and 28-34 have been considered but are moot in view of the new ground(s) of rejection.

3. The rejection of claims 12-28 under 35 USC § 101 is maintained. The methods performed in claims 12-28 need to be attached to an apparatus within the body of the claims.

4. The rejection of claims 23-28 under 35 USC § 112, 2nd paragraph is withdrawn in light of Applicant's amendment.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 12-28 are rejected under 35 U.S.C. 101 based on Supreme Court precedent and recent Federal Circuit decisions. The Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing (Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); and Cochrane v. Deener, 94 U.S. 780,787-88 (1876), In re Bilski, 88 USPQ2d 1385 (Fed. Cir. 2008)).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim should positively recite the other statutory class (the thing or product) to which it is tied. This can be done, for example, by identifying the apparatus that accomplishes the method steps, by positively reciting the subject matter that is being transformed, or by identifying the material that is being changed to a different state.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-22 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenfeld et al. U.S. Patent No. 6,804,656 in view of Shen Pre-Grant Pub No. 2003/0212580.

9. With regards to claim 1, Rosenfeld teaches a system comprising a first interface to a clinical data store (Col. 19 lines 2-44); a second interface to a knowledge base (Col. 5 lines 11-22; col. 22 lines 15-19); and an inference engine to selectively perform comparative analysis of the clinically related data against the knowledge base (Col 4. lines 8-13; col. 5 lines 11-22).

Rosenfeld does not specifically disclose that the comparative analysis projects at least one facility-wide outcome based on an analysis of the clinically related data and a clinical guideline selected from the knowledge base. However, Shen does recite projecting at least one facility-wide outcome (¶ 133). It would have been obvious to one of ordinary skill in the art to combine the teachings of Rosenfeld with those of Shen in order to produced realistic projections. Furthermore the statement, "wherein the comparative analysis projects..." is directed to the intended use/result of the inference engine, and it has been held that, " While

features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function alone (MPEP 2114; In re Swineheart, 169 USPQ 226; In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997)).

Claims 12and 29 are rejected under the analysis of claim 1.

10. With respect 2, Rosenfeld teaches a data warehouse (Col. 7 lines 7-10).

Claims 13 and 30 are rejected under the analysis of claim 2.

11. Claim 3 is rejected as Rosenfeld teaches the data warehouse storing clinically related data from at least one clinical facility (Abstract; Fig. 8A item 9034; Fig. 8B item 9038).

Claims 4, 14 and 15 are rejected under the analysis of claim 3.

12. With respect to claim 5, Rosenfeld teaches the comparative analysis comprising an analysis of at least one key performance indicator (Col. 43 lines 11-53).

Claims 16 and 31 are rejected under the analysis of claim 5.

13. Claims 6 and 7 are rejected as Rosenfeld teaches the knowledge base comprising a set of clinical guidelines with best practices (Col 3. lines 51-55; col. 5 lines 11-22; col. 26 lines 8-17).

Claims 17, 18 are rejected under the analysis of claims 6 and 7.

14. For claim 8, Rosenfeld recites best practices data comprising pharmaceutical and medical procedure information (Col. 7 lines 24-67); and he discloses historical files (Col. 20 lines 42-46). Shen also recites the use of historical outcome information (¶ 134). It would have been obvious to one of ordinary skill to combine the teachings of Rosenfeld and Shen to include historical outcomes information in best practices for reuse when appropriate.

Claim 19 is rejected under the analysis of claim 8.

15. Claim 9 is rejected as Shen discloses the facility-wide outcome comprising a financial outcome, an operational outcome or a clinical outcome corresponding with a plurality of patients or a combination thereof (¶ 123). It would have been obvious to one of ordinary skill in the art to combine the teachings of Rosenfeld with those of Shen in order to produced realistic projections.

Claims 20 and 32 are rejected under the analysis of claim 9.

16. With respect to claim 10, Rosenfeld discloses maintaining a performance mortality measure (Col. 16 lines 4-6); and outcome algorithms for antibiotic cost information (Col. 7 line 31). Shen also recites clinical cost information (¶ 20, 112). A predictable result of Rosenfeld and Shen would be to include whatever information necessary (e.g. patient mortality and morbidity information, clinical cost information etc.) for informational purposes. (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)). Furthermore, the data contained in the outcome is non-functional descriptive material that does not further limit the process of claim 1 (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claims 21 and 33 are rejected under the analysis of claim 10.

17. Claim 11 is rejected as Rosenfeld teaches storing the comparative analysis (col. 20 lines 1-5).

Claims 22 and 34 are rejected under the analysis of claim 11.

18. Claims 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shen Pre-Grant Pub No. 2003/0212580.

19. With respect to claim 23, Shen discloses a method comprising the steps of receiving a selection of one a plurality of policies and procedures stored within a knowledge base (¶ 20, 57, 85); accessing clinically related data corresponding with a plurality of patients (¶ 100); selectively performing comparative analysis of the clinically related data against the first selected policy or procedure to provide an indication as to whether the first selected policy or procedure has been attained by a medical facility (¶ 100, 110). Furthermore, the language, "to provide an indication…" is directed to the intended result of the step of selectively performing a comparative analysis, and it has been held that a "clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited" (*Minton v. Nat'l Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)).

Shen also recites using selected policy or procedure and clinically related data corresponding with a plurality of patients to perform a predictive analysis that projects at least one operational, financial or facility-wide outcome (¶ 46,133).

Shen does not specifically recite receiving a second selection of one of the plurality of policies; however, this is merely a duplication of the first limitation and it has been held that the "mere duplication of parts has no patentable significance unless a new and unexpected result is produced" (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

20. Claim 24 is rejected, as Shen recites accessing a data warehouse (Abstract, ¶ 42).

21. Claim 25 is rejected, as Shen discloses performing an analysis of at least one key performance indicator (Abstract, ¶ 12).

22. Claim 26 is rejected, as Shen recites a set of clinical guidelines (¶ 57).

23. For claim 28, Shen recites estimated clinical cost information (¶ 20, 112). He does not recites mortality and estimated morbidity information; however, Examiner takes Official Notice that such information was old and well known in the art at the time the invention was made. It would therefore have been obvious to combine the prior art to take into account such data for informational purposes. Furthermore, the data contained in the outcome is non-functional descriptive material that does not further limit the process of claim 23 (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a) Wess Jr., U.S. Patent No. 6,163,781 discloses medical outcomes such as financial, clinical or administrative, mortality and morbidity data.

b) Papageorge U.S. Patent No. 6,584,445 recites output information including cost information depending on mortality and morbidity rates.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295. The examiner can normally be reached on Monday-Friday 7:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VL

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626